

STATEMENT OF WORK -

TITLE: Chemical Engineering Support for EPA's Office of Pollution Prevention and Toxics

BACKGROUND AND OBJECTIVES

The Office of Pollution Prevention and Toxics (OPPT) of the Environmental Protection Agency (EPA) is responsible for work under a number of statutes including the Toxic Substances Control Act (TSCA), and the Pollution Prevention Act of 1990 (PPA). Key programs managed by OPPT include the new chemicals and existing chemicals review programs. The Office also provides technical support to regulatory programs managed by other offices such as the Office of Solid Waste and Emergency Response (OSWER).

The activities of the Office require a number of different types of analyses including assessments of hazard, exposure, risk, pollution prevention opportunities and the economic impact of proposed regulatory actions. The Chemical Engineering Branch (CEB) is one of several groups within the Office that provides technical support to these programs. CEB's areas of expertise include the characterization of methods for manufacturing and using industrial chemicals; and assessments of the potential for occupational exposure and environmental releases resulting from these industrial operations. CEB also identifies methods for reducing the potential for exposure and environmental release. These analyses help the Office to better understand the risks from the chemicals being evaluated and to make decisions on appropriate actions to take.

CEB's mission includes the development and refinement of tools for assessing occupational exposure, environmental release and pollution prevention opportunities. Additionally, there is a significant outreach component as CEB seeks to have these tools reviewed by experts outside the Agency and be available for use by industry, academia, other environmental organizations, and the general public.

SCOPE

The contractor shall provide engineering support services which include assessments of occupational exposure, environmental release, hazard, risk, pollution prevention opportunities, and economic impact of proposed regulatory actions in support of the CEB mission as well as potentially supporting other branches within OPPT in areas defined in the following tasks. The contractor shall provide support in the development of tools for assessing occupational exposure, environmental release and pollution prevention opportunities. The contractor shall provide assistance in outreach activities including the Peer Review of CEB work products and their dissemination to interested parties outside the Agency.

DELINEATION OF TASKS

This statement of work includes both performance-based tasks and level-of-effort based tasks. Each performance-based tasks listed in the SOW also include its performance measures.

For Work Assignments that involve the collection, evaluation, and use of environmental data by and for the Agency, the contractor shall implement a quality system that meets ANSI standard E4-1994 and prepare a quality assurance (QA) project plan for each specific task following OPPT/EPA guidelines.

EPA ORDER 2100.1 of January 14, 2002, entitled "Accessible Electronic and Information Technology" require the U.S. EPA to procure electronic information technology (EIT) services and supplies that conform to the accessibility standards outlined in Section 508 of the Rehabilitation Act of 1973 as Amended in 1998. In the performance of this Contract and all Work Assignments issued against this Contract, the Contractor shall comply with all requirements of the EPA ORDER and the Rehabilitation Act as well as any accessibility standards applicable for EIT services and supplies. Additional guidance and/or technical direction is available from the PO.

Work for Task 1 will need to be done at EPA Headquarters (EPA Building East, 1201 Constitution Avenue, Washington, DC), for reasons discussed below in the Task description. Generally, work for all other tasks will be done off-site after an initial kick-off meeting. Several of the work assignments may involve travel to industrial sites (Task 11) or to conferences and seminars for providing outreach support (Task 10). Authorized travel will be specified in the work assignments.

Performance-Based Tasks

Task 1: Preparation of Draft Initial Review Engineering Reports

Background

Section 5 of the Toxic Substances Control Act (TSCA) requires companies to submit a Premanufacture Notification (PMN) or Low Volume Exemption (LVE) at least 90 days prior to commercial production (including importation) of any chemical that is not already on the TSCA Inventory of Chemicals In Commerce (i.e., "existing chemicals").

The Chemical Engineering Branch (CEB) is responsible for preparing occupational exposure and environmental releases assessments of new chemicals under Section 5 of TSCA. These will include Pre- Manufacture Notices (PMN) Submissions, Low Volume Exemptions (LVE), and Test Market Exemptions (TME). Due to the nature of the review process, a quick turnaround (generally within a few days of receipt of the information from the EPA developed chemistry and hazard reports) is required.

The CEB work product is an Initial Review Engineering Report (IRER). These are screening-level assessments of occupational exposures and environmental releases for new chemical submissions submitted to EPA under TSCA. The assessments are based on readily available information. This will include information provided by the company in the submission,

information obtained from telephone conversations with the submitter technical contact, assessments on past cases that are analogous to the case being reviewed, CEB's Generic scenarios, other models and assessment policies developed by CEB, readily available reference materials, other sources identified by the contractor, and professional engineering judgement.

Data on past cases is in an existing database that will be available to the contractor. Maintenance and updating of this database is done through task 5 of this contract Statement of Work. CEB's generic scenarios are available in electronic and hard copy form. The IRER is CEB's input to the screening-level decision meeting, called the Focus meeting, in EPA/OPPT's New Chemicals Review Process.

Objectives

The objective of this task is to provide chemical engineering support to the Chemical Engineering Branch (CEB) under the Toxic Substances Control Act (TSCA) by preparing draft Initial Review Engineering Reports (IRERs) for new chemicals EPA reviews under TSCA. The IRERs shall be prepared in accordance with procedures specified in a Quality Assurance Project Plan developed by the contractor and approved by EPA. The draft IRERs shall be submitted to EPA/CEB for final review and approval. The reviewed product will be CEB's input to the OPPT New chemical Review process.

Task Description

The contractor shall conduct work for this task in accordance with the procedures for handling TSCA Confidential Business Information (TSCA CBI). This will include obtaining TSCA CBI clearances for appropriate personnel. Because this work assignment requires access to the TSCA CBI LAN system, work must be performed on-site at EPA headquarters. Due to security precautions, the LAN can only be accessed at EPA Headquarters. The contractor will also need to access TSCA CBI at the Confidential Business Information Center located at the EPA East Building at 1201 Constitution Avenue.

The Contractor shall assess the validity of the information provided in the submission and prepare assessments of occupational exposures and environmental releases. See Attachment A for a standard IRER report form. The contractor will be tasked to prepare approximately 900 to 1000 draft IRERs per year. Cases will be typically assigned on Fridays and Tuesdays by the EPA Work Assignment Manager. The contractor will be notified by E-mail. Generally, the contractors will then work on Mondays and Wednesdays to complete the assigned cases. Generally, as few as 4 and as many as 12 cases will be assigned. Each case is expected to be completed in 2 hours or less on average. An additional requirement of this work assignment is that the work assignment be staffed by personnel with a Chemical Engineering degree.

In order to complete the cases, the contractor shall do the following.

- Evaluate methods used to manufacture, process and use the new chemical, in order to assist in identifying potential occupational exposure and environmental release points.
- Estimate occupational exposure (e.g., frequency, duration and magnitude) and environmental release (e.g., frequency and magnitude of releases to treatment, type of treatment

and/or environmental media).

- Report information on use and effectiveness of controls, including personal protective equipment and engineering controls, for reducing exposures and releases.
- Collect and report the physical/chemical properties (e.g., chemical name/category, vapor pressure, water solubility and molecular weight) from the Industrial Chemistry Branch's (ICB's) Chemistry Report (CRSS).
- Collect and report the health and ecotoxicity ratings and concerns from the Structure Activity Team (SAT) report. This report will identify which analyses are required from CEB for both occupational exposure (dermal, inhalation) and environmental release (air, water, landfill, incineration)
- Contact the submitter to obtain additional information not contained in the PMN or LVE submission and/or seeking clarification on information submitted as needed in order to assist in the preparation of the IRER.
- Report critical information from PMN or LVE submission (e.g., production volume; intended uses; number of manufacturing, processing and use sites; number of workers exposed; number of operating days per year during manufacturing, processing and use; amount of PMN or LVE released to the environment; batch sizes and daily amount produced, consumed and/or used in each step in the lifecycle of the new chemical).
- Develop and present a description of process flow for manufacturing, processing and use of the PMN or LVE substance.
- Estimate the number of sites, the number of workers; annual days per year exposed to the PMN or LVE substance; occupational exposures (e.g., inhalation and dermal doses in mg/day) and environmental releases to all media (e.g., water, incineration, landfill, air and underground injection in kg/site-day including the frequency of release (in days/yr)) for manufacturing, processing and use of the PMN or LVE substance.
- Report any critical information on pollution prevention, as provided in the submission.
- Document and report all assumptions, uncertainties, references used and telephone contacts with the submitter.

Performance Measures

Under TSCA, EPA has limited time to complete reviews of new chemical submissions (90 days for PMN cases and 30 days for L cases). The initial screening phase of the review is completed early in the review. It is critical that CEB's work products are completed quickly and efficiently to help facilitate the overall review of the new chemical submission. Performance standards are focused on these objectives.

Performance Standard		
Efficiency #1		
Efficiency #2		
Quality #1		
Quality #2		

Inspection and Acceptance Criteria

At the end of each IRER preparation day, draft IRER reports prepared by the contractor shall be saved on the CBI LAN in the appropriate subdirectory. Hardcopies shall be placed in the designated safe drawer.

Efficiency Standard #1: Hours per case - < 2 hrs

The contractor shall fill out the assignment sheets and indicate the number of hours per case. Spot checks of these assignment sheets will be performed periodically by the EPA WAM or other CEB Staff. These data shall also be provided on the monthly report and will be the basis for evaluation of the efficiency standard. Cases which meet CEB's drop criteria for which abbreviated reports are prepared will be included in the average of hrs/case. An example of a drop category is a case where there is a concern only for potential inhalation exposure and due to factors such as vapor pressure, physical state as handled, method of application, the potential for inhalation exposure to vapor, particulate, or mist is expected to be negligible.

Efficiency Standard #2: >90% of cases completed on time

All new chemical submissions will be ready for the contractor at the beginning of each IRER preparation day. The objective is for the contractor to complete the IRER for each case assigned. The contractor shall indicate on the assignment sheet if any cases were not completed and need to be delayed. The contractor shall document the reason for each day. Cases delayed due to significant data gaps where an effort has been made to contact the submitter in a timely manner will not be counted for this standard. Significant data gaps include confusing, conflicting or limited information was presented in the submission such that even conservative default assumptions or generic scenarios could not be reasonably applied. Data on the total number of cases assigned and the number of delayed cases will be used as a basis for calculating the percent completed on time.

Quality Standard #1: cases with Major Errors - greater than 90% with no major errors

EPA/CEB staff will review each IRER report and do a quality review. Unsatisfactory performance will be documented. A major error is one where significant revision needs to be made by the CEB reviewing engineer. For example, if the CEB engineer would need to rewrite major portions of the assessment of manufacture or if an assessment of an industrial use was omitted. The CEB reviewing engineer will provide documentation to the EPA WAM of cases that do not meet this standard.

Quality Standard #2: Cases with Minor Errors - greater than 90% with 3 or fewer minor errors

Minor errors may be errors in an individual calculations such as an estimate of water release during

manufacture, formatting errors such as the wrong case # at the top of page, or neglecting to fill out a part of the IRER form such as the Occupational Exposure Ranking. Minor errors such as these impact the quality of the CEB assessment product and its ease of use by other members of the OPPT New Chemicals Review program. For this purpose, minor errors will not include minor misspelling, or minor grammatical errors. The CEB engineer will provide documentation to the EPA WAM of cases that do not meet this standard.

The performance data will be summarized for each performance standard for each monthly reporting period. Based on the results of the collection and review of this data, the government will withhold the amounts from the next submitted invoice. The \$ amount of the fee reduction will be based on the percentage reductions listed below applied to the fee charged for that month.

Performance Standard Efficiency Standard #1 - hrs/case

Efficiency Standard # 2 - cases completed on time

Quality Standard #1 - cases with major errors

Quality Standard #2 - cases with minor errors

Performance-Based Tasks

Task 2: Preparation of Quality Certified Generic Scenarios

Background

The Chemical Engineering Branch (CEB) in the Economics, Exposure and Technology Division (EETD) of EPA's Office of Pollution Prevention and Toxics (OPPT) is responsible for preparing assessments of occupational exposure and environmental release for new and existing chemicals that EPA reviews under the Toxic Substances Control Act (TSCA). In most cases, data on the actual chemical being assessed is not available. This has caused CEB to rely on other approaches for developing exposure and release assessments.

One important tool that CEB uses are "generic scenarios". Generic scenarios present standard approaches for estimating exposures and releases for a particular category of chemicals processed or used in a specified industry (Ex. chemicals present in liquid and powder detergents used in industrial and commercial laundries). They are based on the most current, readily available data and estimation approaches, and ideally, incorporate input from technical experts outside of CEB.

To date, CEB and its contractors have developed approximately 60 generic scenarios that cover a wide range of chemical use categories and industries. They have proved to be an invaluable data source in preparing assessments for a number of EPA/OPPT programs, in particular the new chemicals review program

The first key stage in generic scenario development is preparing scenarios that meet CEB's quality criteria. Once a scenario has attained this measure of quality, it is ready for use by CEB in engineering assessments. It is also ready to be sent to experts outside the Agency for external peer review.

Objectives

CEB has undertaken an effort to update and upgrade the quality of its generic scenarios. The objective of this program is to develop generic scenarios that meet CEB's Generic Scenarios quality criteria.

Task Description

The EPA WAM will make assignments of current CEB generic scenarios that need to be upgraded in quality or new industry categories for which a generic scenario needs to be developed. Generally, there will be 15 scenarios assigned over the course of a year. The

contractor shall develop quality-certified scenarios. Quality- certified scenarios meet the following 3 specifications.

1. The scenarios scope has been formally approved by the EPA WAM. Quality Criteria for a scoping document are provided in Appendix B. Once there is an approved scope, the EPA WAM will set the target date. Generally it will be 4 weeks after assignment.
2. The scenario meets all of CEB's Generic Scenarios Quality Criteria. The most current version of these criteria are provided in Attachment C. The Quality Criteria are occasionally updated, generally no more than twice per year. These updates are generally done with contractor input and will be formally issued by the EPA WAM. The contractor will deliver the scenarios in hardcopy format (3 or more copies as specified by the EPA WAM), and electronic format. The contractor will develop the scenarios in Word. The contractor will also provide a copy of a checklist certifying that all the QC criteria have been met. Quality-Certified Scenarios shall be delivered to the EPA WAM. CEB will then conduct its own internal review. The EPA WAM will summarize comments for the contractor to incorporate. The third specification for quality-certified scenarios is:

3. All comments from CEB's internal review have been incorporated into a revised Draft version. The EPA WAM will set the target date. Generally it will be 2 weeks after comments have been issued.

Performance Measures

Generic scenarios are key sources of technical input to CEB staff in preparing assessments for chemicals EPA reviews under TSCA. CEB staff require quality data sources already on-hand to meet the various needs in OPPT which often require short turnaround times. To meet this need, it is important that generic scenarios are completed in a timely manner at a high standard of quality. Performance standards are focused on these objectives.

Performance StandardTimeliness

Quality

Inspection and Acceptance Criteria

The EPA WAM will maintain a project tracking table which will list the assignments and the target dates. The contractor shall deliver completed QC certified scenarios to the EPA WAM. The normal standard for delivery will be an electronic copy by E-mail and 3 hardcopies.

Performance Standard #1: Timeliness - QC certified Generic Scenario and Incorporation of Comments completed within one week of initially agreed upon target date.

As specified in the Task description, The EPA WAM will make assignments of the industry categories for which

generic scenarios shall be developed. Generally, at this time, a scoping document will have already been prepared by the contractor and reviewed and approved by CEB. The target date for completing the scenario will generally be 4 weeks after assignment. The contractor shall deliver the QC-certified scenario and a QC checklist to the EPA WAM. When both have been delivered, delivery will be considered complete. These dates will be tracked by the WAM and used as the basis for evaluating this criteria.

After receipt of the scenario, CEB will conduct its internal review and provide comments for the contractor to incorporate. At this time, a date will be set for delivery of the revised scenario. This date and the actual delivery date will be tracked by the WAM and used as the basis for evaluating this criteria.

Performance Standard #2: Quality - CEB QC check - No more than 3 QC criteria not met.

Once received at EPA, the EPA WAM and other CEB Staff will review the criteria using the Quality Criteria checklist. CEB will do their own independent evaluation of whether all the quality criteria are met. This review will be documented. Any determinations made by CEB reviewers that a quality criteria is not met will be documented in detail. This will be used as the basis for evaluating successful completion of the quality acceptance criteria. When a revised draft scenario is delivered, CEB will also review and evaluate to make sure any Quality Criteria that were not met in the Draft version have now been met.

Evaluations will be done on a quarterly basis. The performance data will be summarized for each generic scenario prepared during the evaluation period. CEB will require an estimate from the contractor of the fee for this task for the evaluation period. The \$ amount of the fee reduction will be then be based on the performance data for each scenario and the percentage reductions listed below.

Performance StandardPerformance Standard #1 - timeliness

Performance Standard #2 - Quality

Level-of-Effort Based Tasks

TASK 3:General Support for Environmental Release Assessment

The contractor shall evaluate the methods of manufacture, processing, and uses of an existing or new chemical substances, including microorganisms, to quantify the potential routine and accidental releases of the substances to the environment (e.g. air, water, land). Generally, work will be performed off-site and Kick-off meetings will be held at the beginning of the work assignments.

To assess environmental releases, the contractor shall provide technical support in the areas of environmental release assessments, which includes the following subtasks:

- 3.1 Identify the unit operations during manufacture, processing and use of chemical substances for which routine and accidental releases to the environment may occur.

3.2 Estimate the duration, in hours per day, and frequency (days/year) of routine releases.

3.3 Assess the probability of releases as a result of a chemical accident.

3.4 Estimate the number of sites where such releases occur.

3.5 Using standard CEB methods or other available data or methods, estimate or model the volume of daily release, in kilograms per site per day to air and water and the release to other environmental medium of total annual release (kg/year).

3.6 Characterize the uncertainties associated with the releases assessment and identify priorities in developing additional data and how this data would improve the assessment.

3.7 Identify and evaluate pollution prevention and/or risk reduction technologies and practices that are being used or could be used by industry to eliminate or reduce the amounts of chemicals and ancillary byproducts and wastes released to the environment or transferred offsite. The order of preference of these technologies should be source reduction, recycling, treatment, and disposal.

3.8 Evaluate the effectiveness, cost, and environmental and exposure impacts of risk reduction alternatives to mitigate releases, reduce waste generation, and reduce the probability of an accidental release.

3.9 Identify those areas that are lacking cost-effective risk reduction technologies which might, therefore, be amenable to further research.

3.10 Determine how the wastes containing the chemical(s) of concern are disposed of at the manufacturing, processing, and user sites, for example, by on-site water treatment plant or incineration.

3.11 Determine the effectiveness of various treatment or control technologies. Assess the transport of the chemical in the various environmental media (air, water, land).

TASK 4:General Support for Occupational Exposure Assessment

The contractor shall evaluate the operations involved in the manufacturing, processing, and uses of existing or new chemical substances including genetically engineered microorganisms in order to characterize occupational exposures. Generally, work will be performed off-site and Kick-off meetings will be held at the beginning of the work assignments.

To characterize exposures to identified chemical substances, including genetically engineered microorganisms, the contractor shall provide technical support in the areas of occupational exposure assessments, which includes the following subtasks:

4.1Develop and describe in detail the most probable or existing process routes for the manufacture, processing, and use of the chemical substance(s). This shall include the development of a simple process flow diagram indicating the unit operations associated with each process route, an indication of whether the processes are batch or continuous, specification of the equipment used, and an indication of degree of automation of the processes.

4.2Determine the worker activities and unit operations where there is a potential for release and exposure for each process route.

4.3Determine the potential routes of exposure (e.g. dermal and inhalation).

4.4Determine the number of sites where exposure may occur and the worker populations potentially exposed during each activity associated with the chemical substance.

4.5Estimate the duration, in hours per day, that workers are potentially exposed in each activity noted above.

4.6Estimate the frequency, in days per year, that workers are potentially exposed in each activity noted above.

4.7Using standard CEB methods, or other available data or methods, estimate the potential inhalation exposure levels in the workplace, in milligrams per cubic meter or parts per million, for the substance of concern for each activity. Also, express these exposure levels in terms of potential dose rates (PDRs), lifetime average daily doses (LADDs), or other units using standard CEB equations and appropriate parameters.

4.8Assess the adequacy and comparability of data collected by different analytical techniques.

4.9Estimate the amount of substance available for dermal contact during each activity and the potential dermal dose rate.

4.10 Assess the potential exposures both inhalation and dermal to workers and off-site personnel from non-routine activities such as maintenance, spills and accidental releases.

4.11Characterize the uncertainties associated with the workplace exposure assessment and identify priorities in developing additional data and how this data would improve the assessment.

4.12 Based on limited information, identify and evaluate the effectiveness of current and alternative engineering controls, chemical substitution, operating practices, and personal protective equipment used in industrial and commercial settings to mitigate worker exposure to

chemical substances. The contractor shall assess the capital and annual operating costs of these controls and their impact on worker safety.

4.13 Identify and evaluate the effectiveness and cost of innovative changes to the manufacture, processing, and use of the chemical that may reduce occupational exposures, waste generation or the probability of an accidental release of a chemical substance.

TASK 5: Development of ChemSTEER and Other Computerized Assessment and Database Support

The contractor shall provide assistance in the continued development of the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) and Other Computerized Assessment Tools. ChemSTEER is a software package that integrates CEB's methodologies for estimating occupational exposures and environmental releases into a single software package. The contractor will be supplied the most current version of the software (also available on EPA's Exposure website (www.epa.gov/opptintr/exposure)). Aspects of ChemSTEER support and other computerized assessment and database support may require access to CBI information on the TSCA CBI LAN system. In these instances, work will be required to perform on-site at the EPA East Building. Non-CBI work will be done off-site.

Subtasks shall include but are not limited to:

5.1 Making improvements to existing functions and operations in ChemSTEER. This may include correcting problems, performing testing, and making other improvements as specified by EPA WAMs in work assignments.

5.2 Adding operations, functions, and methods to ChemSTEER. This shall include the programming of newly developed industry specific generic scenarios.

5.3 Improving the Help System in ChemSTEER. The Help system contains information to guide users to understand and use the features and models in ChemSTEER.

5.4 Improving the ChemSTEER Demo/Tutorial and Developing Training Materials.

5.5 The development of ChemSTEER is part of a larger effort by EPA's OPPT to integrate its analytical tools into a single environment. The contractor shall develop Data Transfer programs to transfer selected data from/to Lotus Notes or other types of data management formats.

5.6 Maintaining Documentation for the development of ChemSTEER. This shall include all technical documentation as well as the functional specification including details of system design, software platform and hardware requirements.

5.7 Development of other computerized tools and databases for estimating occupational exposures and environmental releases. For example, maintenance and updating of a database that contains information on all past IRERs completed by CEB since 1993.

Task 6:Support for Peer Review

An important component of EPA's commitment to sound science is Peer Review. Many of CEB's scientific and technical work products will undergo peer review. Subtasks shall include but are not limited to:

6.1 Assist in preparation of materials to be peer reviewed. This shall include the charge that the peer reviewers are to respond to.

6.2Working with the EPA WAM to develop a list of qualified peer reviewers as defined in the work assignment.

6.3 Contacting selected peer reviewers and making arrangements for appropriate materials to be delivered.

6.4Preparing comment summaries and draft and final evaluation reports.

6.5 Other tasks as designated in the work assignment to complete a Peer Review that meets Agency standards.

TASK 7:Use Clusters and Other Ranking System

The contractor shall provide technical support in the areas of chemical ranking and prioritization. Subtasks shall include but are not limited to:

7.1 The contractor shall perform technical analyses and develop use profiles of industrial and commercial chemicals. The profiles include collecting exposure and hazard related information during the manufacture, process and use of the chemicals. In addition, the contractor shall collect information on potential hazards of the chemicals.

7.2The contractor shall provide technical support to EPA for the development of chemical ranking systems. This involves activities such as collection and analyses of data, participation in scoping meetings, computer system design and system documentation and maintenance.

7.3The contractor shall provide technical support to EPA in marketing and disseminating information from the ranking systems. This involves activities such as preparation and presentation of data outreach materials and distribution of systems to various interested parties.

TASK 8:Green Engineering, DFE and Other Pollution Prevention Support

The contractor shall provide technical support to OPPT's Green Engineering, Design for Environment (DFE) and other Pollution Prevention related programs. Subtasks shall include but are not limited to:

8.1Support the development of the Green Engineering textbook ("Green Engineering - Environmentally Conscious Design of Chemical Processes"), and other such educational materials.

8.2 Research on the current state-of-the-art approaches and methods in Green Engineering including research on software that integrates pollution prevention and risk reduction considerations into chemical process design.

8.3 Other tasks as designated in the Work Assignments in support of these programs objectives of contributing to reductions in exposure, environmental release and overall risk associated with chemicals.

TASK 9: Research and Estimation Methodology Development

The contractor shall provide technical support in the areas of exposure and release assessment research, which includes the following subtasks:

9.1 The contractor shall perform research (literature searches) to identify state-of-the-art assessment methodologies (e.g. chemical screening, dermal exposure assessment, inhalation exposure assessment, waste treatment systems, hazard assessment, risk assessment, and uncertainty analysis) and develop new assessment methodologies based on the results of the research.

9.2 The contractor shall update / upgrade current CEB exposure and release assessment methodologies.

9.3 The contractor shall perform research to improve CEB's industrial hygiene/safety assessment support capabilities. This includes research in the areas of:

9.3.1 dermal and inhalation exposure assessment,

9.3.2 statistical analysis of monitoring data,

9.3.3 analytical methods for measuring exposure levels,

9.3.4 effectiveness of personal protective equipment (i.e. respirators, gloves), engineering controls (i.e. ventilation) and work practices in reducing the potential for exposure, and,

9.3.5 safety engineering (impact of equipment, work practices, chemical substitution on worker safety).

TASK 10: General Outreach and Presentation Support

The contractor shall provide general outreach and presentation support. Subtasks shall include but are not limited to:

10.1 The contractor shall produce outreach support documents, including but not limited to posters, pamphlets, brochures, and training materials for the Chemical Engineering Branch. This may also include the enhancement, updates, reformatting of an internet site. For example, the Green Engineering Web site (www.epa.gov/oppt/greenengineering).

10.2 The contractor shall provide multimedia presentation support to EPA. Multimedia

presentations may include PC-based presentations, 35mm slides, overhead projector slides and Internet postings.

TASK 11:Industrial Site Visits

The contractor shall conduct visits of perform surveys of industrial sectors to improve EPA's understanding of "real world" industrial practices. For example, visits of Auto refinishing facilities to gather information on baseline shop practices and technologies. The objective of these visits includes identifying the following:

11.1Methods for manufacturing, processing and use of chemicals.

11.2Worker activities and worker protection practices.

11.3Sources of environmental release.

11.4Methods for treatment, and disposal of wastes.

11.5Pollution practices being employed.

TASK 12:Provide Support for Regulatory Development

CEB provides technical support to many regulatory activities of OPPT. Under this task, the contractor shall provide technical support to assist CEB and other branches in OPPT in providing technical support for the regulatory activities of OPPT. This shall include but is not limited to the following subtasks:

12.1Conduct technical research and perform analyses. For example, research on containment practices used in closed-system fermentation facilities assisted CEB in making recommendations for the Biotechnology rule.

12.2Providing support for developing, updating and revising guidance documents. For example, revising an Instruction Manual for filling out the TSCA Inventory Update Reporting Rule based on public comment and EPA internal review and discussion.

ATTACHMENT A - IRER Report Form

INITIAL REVIEW ENGINEERING REPORT

CBI: Yes

LVE/PMN: _____ ENGINEER: _____

PV (kg/yr):

SUBMITTER:

USE: _____

OTHER USES:

MSDS: _____ Yes/No _____ Label: _____

Yes/No

General Eqp.:

Respirator:

Health Effects:

TLV/PEL (PMN or raw materials):

LVE/PMN PPE:

CRSS:

Chemical Category:

VP:

S-H₂O:

MW:

Phys State:

Consumer Use: Yes/No _____

SAT (concerns):

Ground Water:

Health:

Eco:

PBT:

INITIAL REVIEW ENGINEERING REPORT

CBI: Yes

LVE/PMN:

OCCUPATIONAL EXPOSURE RATING:

ASSUMPTIONS:

POLLUTION PREVENTION CONSIDERATIONS:

EXPOSURE-BASED REVIEW: Yes/No (
criteria met)

- 1) # of workers exposed (>1,000): Yes/No
2) >100 workers with >10 mg/day inhalation exposure : Yes/No
3) (a) >100 workers w/1-10 mg/day inh. exp. & >100 days/yr: Yes/No
(b) Routine Dermal Cont: >250 workers & >100 days/yr: Yes/No

INITIAL REVIEW ENGINEERING REPORT

CBI: Yes

LVE/PMN:

MFG:

Site/Location:

Days/yr:

basis:

Process Description:

ENVIRONMENTAL RELEASES (Eqpt. cleaning, container
residue, etc.):

WATER:

Basis:

AIR:

INCINERATION:

from:

Basis:

LANDFILL:

INITIAL REVIEW ENGINEERING REPORT

CBI: Yes

LVE/PMN:

MFG (CONT):

OCCUPATIONAL EXPOSURE

Tot. # of workers:

Days/yr:

Inhalation:

Number of workers with inhalation exposure:

Basis:

Inhalation Monitoring Data Review

1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): Yes/No

2) a) Exposure level > 1 mg/day? Yes/No

OR

b) Hazard rating for health of 2 or greater? Yes/No

Inhalation Monitoring data desired? **Yes/No**

Dermal: contact with liquids:

Up to % concentration

Basis:

INITIAL REVIEW ENGINEERING REPORT

CBI: Yes

LVE/PMN:

PROC/USE:

Site/Location:

Days/yr:

Process Description:

ENVIRONMENTAL RELEASES (Eqpt. cleaning, container
residue, etc.):

WATER:

from:

to:

Basis:

AIR:

INCINERATION:

from:

basis:

LANDFILL:

INITIAL REVIEW ENGINEERING REPORT

CBI: Yes

LVE/PMN:

PROC/USE (CONT):

OCCUPATIONAL EXPOSURE

Tot. # of workers:

Days/yr:

Inhalation:

Number of workers with inhalation exposure:

Basis:

Inhalation Monitoring Data Review

1)Uncertainty (estimate based on model, regulatory limit, or data not specific to industry):Yes/No

2)a)Exposure level > 1 mg/day?Yes/No

OR

b)Hazard rating for health of 2 or greater?Yes/No

Inhalation Monitoring data desired?YES/No

Dermal:contact with liquids:

Up to % concentration

Basis:

CBI CONTACT REPORT
(Telephone Log)

LVE/PMN:

Call By:

Call To:

Submitter:

Date:

Time:

Q1:

A1:

ATTACHMENT B - CEB Generic Scenario

Quality Criteria for Scoping Documents

2/12/03

1. _____ Provides a recommendation for what the scenario will cover
(products, industry, _____ functional components). Provides rationale for this
recommendation.

2. _____ Provides general process descriptions

3. _____ Identifies primary release sources that will be assessed.

4. _____ Identifies primary sources of exposure that will be assessed.

5. _____ Provides results of preliminary literature search including results
from search of _____ EPA, OSHA, NIOSH, OECD and trade journals

Scoping Document Approval:

_____ (Name)

_____ (Date)

ATTACHMENT C: CEB Generic Scenario Quality Criteria - 10/31/03

A. Product Transparency

1. Does the product clearly state its purpose
2. Does the product provide an explanation of its potential uses?
3. Does the product explain:
 - a. The sources of data used
 - b. The scope of the analysis and/or the methodology followed.
4. Does the product clearly state the strengths and weaknesses of the information and the accuracy (Quality) of the source data used?
5. Does the product contain the basic contact information?
6. Does the product title adequately describe its contents.

B. Scenario Definition

7. Identifies the scope of the scenario (product, industry, covered chemicals). Makes it clear which chemicals are covered and which are not.

Example (from "Photoresist Use in Semiconductor Manufacture")

"This generic scenario presents a standardized approach to estimate potential occupational exposure and environmental releases from non-volatile chemicals present within photoresist materials in the manufacture of semi- conductors. Photoresists are polymer-based liquids applied in layers to create patterns on the silicon wafer. They are comprised of photo-active compounds, resin, stabilizers, polymerization inhibitors, viscosity control agents, dyes, plasticizers, and solvents. This generic scenario may be applied to any of these components with the exception of solvent compounds. "

8. Describes the covered chemicals and provides additional key characteristics. (Ex. CFC substitutes used as blowing agents: What is a blowing agent?; What are typical % in the foam; What are the key properties that make it work (ex. volatility)). Provides information on pchem properties of the covered chemicals.
9. Defines segment of the industry being assessed (i.e. is there a particular segment of the commercial laundry industry being covered)

C. Process Information

10. Provides an approach for estimating the throughput, use rate, amount manufactured of the covered chemicals in kg/site-day for a "typical" or "model" facility in this industry segment to serve as a basis for estimating the number of sites. Provides an estimate of the total number of days/yr of operation. Provides an approach to correct the total number of days for the % associated with the chemical of interest. Estimation approaches specify recommended defaults for each parameter.

11. Describes the path of the covered chemicals from the point of entry into the facility to the point of exit and all the key steps in-between. This includes transport containers. Provides detailed process flow diagram that specifies for the covered chemicals all the steps from point of entry to the facility to the point of exit and indicates all potential worker exposure points and sources of environmental release.

12. Provides sufficient detail for each estimation approach that it could be reproduced by the reader. Interpretations and manipulations of data are clearly explained. Technical rationale provided for all assumptions.

D. Environmental Release Assessment

13. Completes a mass balance for the chemical over the entire facility. Interrelationship of release sources is accounted for.

14. Identifies all potential release sources.

15. Identifies the media of release for each release source

16. Presents an estimation approach for each release source. Standard CEB models are specified by name. Estimation approaches specify recommended defaults for each parameter

17. Provides sufficient detail for each estimation approach that it could be reproduced by the reader. Interpretations and manipulations of data are clearly explained. Technical rationale provided for all assumptions. Deviations from standard CEB estimation techniques are noted and explained.

18. Provides information to the extent possible to characterize the estimation approach

19. Documented effort to obtain and use recent emission data All standard sources identified in the Reference Search SOP have been investigated. Documentation specifies what was searched and the results.

20. Describes on-site control technologies and provides information on treatment efficiencies and describes typical off-site treatment practices.

E. Worker Exposure Assessment

21. Presents a documented approach for estimating the total number of workers with a realistic potential of exposure to the chemicals being assessed.

22. Presents documented assumptions on the number of days/yr of potential exposure and the number of hrs and shifts per day at the facility

23. Identifies all key worker activities and describes our understanding of what the workers actually do

24. Provides estimation approaches for inhalation exposure, dermal exposure and the number of workers for each worker activity. Standard CEB models are specified by name. Estimation approaches specify recommended defaults for each parameter

25. Provides sufficient detail for each estimation approach that it could be reproduced by the reader. Interpretations and manipulations of data are clearly explained. Technical rationale provided for all assumptions. Deviations from standard CEB estimation techniques are noted and explained.

26. Provides information to the extent possible to characterize the approach or data

27. Documented effort to obtain and use recent exposure data. All standard sources identified in the Reference Search SOP have been investigated. Documentation specifies what was searched and the results.

28. Describes engineering controls and PPE typically used.

F. Additional Criteria

29. Dimensional analysis of equations and all units checked for accuracy. Parameter abbreviations used in equations are from the most recent version of the approved list of parameters. Parameters will follow the OECD convention summarized in the guidance document:

“Supplement to the methodology for risk Evaluation - Proposal for the formats of names, parameters, variables, units and symbols to be used in emission scenario documents” - December 2000

30. Detailed example provided as an appendix

31. Document follows most recent version of the standard format.

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